

this per quarter maximum number of samples if doing so is necessary to ensure adequate quality control of employers or consortiums with very large numbers of employees.

(3) For employers with 2000 or more covered employees, approximately 80 percent of the blind performance test samples shall be blank (i.e., containing no drug or otherwise as approved by a DOT agency) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the employer is testing. This paragraph shall not be construed to prohibit spiking of other (potentially interfering) compounds, as technically appropriate, in order to verify the specificity of a particular assay.

(4) Employers with fewer than 2000 covered employees may submit blind performance test specimens as provided in paragraph (d)(3) of this section. Such employers may also submit only blank samples or may submit two separately labeled portions of a specimen from the same non-covered employee.

(5) Consortiums shall be responsible for the submission of blind samples on behalf of their members. The blind sampling rate shall apply to the total number of samples submitted by the consortium.

(6) The DOT agency concerned shall investigate, or shall refer to DHHS for investigation, any unsatisfactory performance testing result and, based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individual responsible for the day-to-day management and operation of the drug testing laboratory. Then the DOT agency shall send the document to the employer as a report of the unsatisfactory performance testing incident. The DOT agency shall ensure notification of the finding to DHHS.

(7) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the employer shall promptly notify the DOT agency concerned. The DOT agency and the employer shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future, and, if there is reason to believe the error could have been systemic, the DOT agency may also require review and reanalysis of previously run specimens.

(8) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the employer shall instruct the laboratory to submit all quality control data from the batch of specimens which included the false positive specimen to the DOT agency concerned. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's urine drug testing. The DOT agency concerned may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the DOT agency, DHHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

#### **§ 40.33 Reporting and review of results.**

(a) *Medical review officer shall review confirmed positive results.* (1) An essential part of the drug testing program is the final review of confirmed positive results from the laboratory. A positive test result does not automatically identify an employee/applicant as having used drugs in violation of a DOT agency regulation. An individual with

#### § 40.33

a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the Medical Review Officer (MRO) prior to the transmission of the results to employer administrative officials. The MRO review shall include review of the chain of custody to ensure that it is complete and sufficient on its face.

(2) The duties of the MRO with respect to negative results are purely administrative.

(b) *Medical review officer—qualifications and responsibilities.* (1) The MRO shall be a licensed physician with knowledge of substance abuse disorders and may be an employee of a transportation employer or a private physician retained for this purpose.

(2) [Reserved]

(3) The role of the MRO is to review and interpret confirmed positive test results obtained through the employer's testing program. In carrying out this responsibility, the MRO shall examine alternate medical explanations for any positive test result. This action may include conducting a medical interview and review of the individual's medical history, or review of any other relevant biomedical factors. The MRO shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally prescribed medication. The MRO shall not, however, consider the results or urine samples that are not obtained or processed in accordance with this part.

(c) *Positive test result.* (1) Prior to making a final decision to verify a positive test result for an individual, the MRO shall give the individual an opportunity to discuss the test result with him or her.

(2) The MRO shall contact the individual directly, on a confidential basis, to determine whether the employee wishes to discuss the test result. A staff person under the MRO's supervision may make the initial contact, and a medically licensed or certified staff person may gather information from the employee. Except as provided in paragraph (c)(5) of this section, the MRO shall talk directly with the employee before verifying a test as positive.

#### 49 CFR Subtitle A (10–1–00 Edition)

(3) If, after making all reasonable efforts and documenting them, the MRO is unable to reach the individual directly, the MRO shall contact a designated management official who shall direct the individual to contact the MRO as soon as possible. If it becomes necessary to reach the individual through the designated management official, the designated management official shall employ procedures that ensure, to the maximum extent practicable, the requirement that the employee contact the MRO is held in confidence.

(4) If, after making all reasonable efforts, the designated management official is unable to contact the employee, the employer may place the employee on temporary medically unqualified status or medical leave.

(5) The MRO may verify a test as positive without having communicated directly with the employee about the test in three circumstances:

(i) The employee expressly declines the opportunity to discuss the test;

(ii) Neither the MRO nor the designated employer representative, after making all reasonable efforts, has been able to contact the employee within 14 days of the date on which the MRO receives the confirmed positive test result from the laboratory;

(iii) The designated employer representative has successfully made and documented a contact with the employee and instructed the employee to contact the MRO (see paragraphs (c)(3) and (c)(4) of this section), and more than five days have passed since the date the employee was successfully contacted by the designated employer representative.

(6) If a test is verified positive under the circumstances specified in paragraph (c)(5) (ii) or (iii) of this section, the employee may present to the MRO information documenting that serious illness, injury, or other circumstances unavoidably prevented the employee from being contacted by the MRO or designated employer representative (paragraph (c)(5)(ii) of this section) or from contacting the MRO (paragraph (c)(5)(iii) of this section) within the times provided. The MRO, on the basis of such information, may reopen the verification, allowing the employee to

present information concerning a legitimate explanation for the confirmed positive test. If the MRO concludes that there is a legitimate explanation, the MRO declares the test to be negative.

(7) Following verification of a positive test result, the MRO shall, as provided in the employer's policy, refer the case to the employer's employee assistance or rehabilitation program, if applicable, to the management official empowered to recommend or take administrative action (or the official's designated agent), or both.

(d) *Verification for opiates; review for prescription medication.* Before the MRO verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). (This requirement does not apply if the employer's GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine.)

(e) In a situation in which the employer has used the single sample method of collection, the MRO shall notify each employee who has a confirmed positive test that the employee has 72 hours in which to request a reanalysis of the original specimen, if the test is verified positive. If requested to do so by the employee within 72 hours of the employee's having been informed of a verified positive test, the Medical Review Officer shall direct, in writing, a reanalysis of the original sample. The MRO may also direct, in writing, such a reanalysis if the MRO questions the accuracy or validity of any test result. Only the MRO may authorize such a reanalysis, and such a reanalysis may take place only at laboratories certified by DHHS. If the reanalysis fails to reconfirm the presence of the drug or drug metabolite, the MRO shall cancel the test and report the cancellation and the reasons for it to the DOT, the employer and the employee.

(f)(1) In situations in which the employer uses the split sample method of collection, the MRO shall notify each employee who has a confirmed positive test that the employee has 72 hours in which to request a test of the split specimen, if the test is verified as posi-

tive. If the employee requests an analysis of the split specimen within 72 hours of having been informed of a verified positive test, the MRO shall direct, in writing, the laboratory to provide the split specimen to another DHHS-certified laboratory for analysis. If the analysis of the split specimen fails to reconfirm the presence of the drug(s) or drug metabolite(s) found in the primary specimen, or if the split specimen is unavailable, inadequate for testing or untestable, the MRO shall cancel the test and report cancellation and the reasons for it to the DOT, the employer, and the employee.

(2) If the analysis of the split specimen is reconfirmed by the second laboratory for the presence of the drug(s) or drug metabolites(s), the MRO shall notify the employer and employee of the results of the test.

(g) If an employee has not contacted the MRO within 72 hours, as provided in paragraphs (e) and (f) of this section, the employee may present to the MRO information documenting that serious illness, injury, inability to contact the MRO, lack of actual notice of the verified positive test, or other circumstances unavoidably prevented the employee from timely contacting the MRO. If the MRO concludes that there is a legitimate explanation for the employee's failure to contact the MRO within 72 hours, the MRO shall direct that the reanalysis of the primary specimen or analysis of the split specimen, as applicable, be performed.

(h) When the employer uses the split sample method of collection, the employee is not authorized to request a reanalysis of the primary specimen as provided in paragraph (e) of this section.

(i) *Disclosure of information.* Except as provided in this paragraph, the MRO shall not disclose to any third party medical information provided by the individual to the MRO as a part of the testing verification process.

(1) The MRO may disclose such information to the employer, a DOT agency or other Federal safety agency, or a physician responsible for determining the medical qualification of the employee under an applicable DOT agency regulation, as applicable, only if—

#### § 40.35

(i) An applicable DOT regulation permits or requires such disclosure;

(ii) In the MRO's reasonable medical judgment, the information could result in the employee being determined to be medically unqualified under an applicable DOT agency rule; or

(iii) In the MRO's reasonable medical judgment, in a situation in which there is no DOT agency rule establishing physical qualification standards applicable to the employee, the information indicates that continued performance by the employee of his or her safety-sensitive function could pose a significant safety risk.

(2) Before obtaining medical information from the employee as part of the verification process, the MRO shall inform the employee that information may be disclosed to third parties as provided in this paragraph and the identity of any parties to whom information may be disclosed.

[54 FR 49866, Dec. 1, 1989, as amended at 59 FR 7356, Feb. 15, 1994; 61 FR 37699, July 19, 1996]

#### § 40.35 Protection of employee records.

Employer contracts with laboratories shall require that the laboratory maintain employee test records in confidence, as provided in DOT agency regulations. The contracts shall provide that the laboratory shall disclose information related to a positive drug test of an individual to the individual, the employer, or the decisionmaker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the individual and arising from a certified positive drug test.

#### § 40.37 Individual access to test and laboratory certification results.

Any employee who is the subject of a drug test conducted under this part shall, upon written request, have access to any records relating to his or her drug test and any records relating to the results of any relevant certification, review, or revocation-of-certification proceedings.

#### § 40.39 Use of certified laboratories.

(a) Except as provided in paragraph (b) of this section, employers subject to this part shall use only laboratories certified under the DHHS "Mandatory

#### 49 CFR Subtitle A (10-1-00 Edition)

Guidelines for Federal Workplace Drug Testing Programs," April 11, 1988, and subsequent amendments thereto.

(b) Employers subject to this part may also use laboratories located outside the United States if—

(1) The Department of Transportation, based on a written recommendation from DHHS, has certified the laboratory as meeting DHHS laboratory certification standards or deemed the laboratory fully equivalent to a laboratory meeting DHHS laboratory certification standards; or

(2) The Department of Transportation, based on a written recommendation from DHHS, has recognized a foreign certifying organization as having equivalent laboratory certification standards and procedures to those of DHHS, and the foreign certifying organization has certified the laboratory, pursuant to those equivalent standards and procedures.

[61 FR 37016, July 16, 1996]

#### Subpart C—Alcohol Testing

SOURCE: 59 FR 7357, Feb. 15, 1994, unless otherwise noted.

#### § 40.51 The breath alcohol technician.

(a) The breath alcohol technician (BAT) shall be trained to proficiency in the operation of the EBT he or she is using and in the alcohol testing procedures of this part.

(1) Proficiency shall be demonstrated by successful completion of a course of instruction which, at a minimum, provides training in the principles of EBT methodology, operation, and calibration checks; the fundamentals of breath analysis for alcohol content; and the procedures required in this part for obtaining a breath sample, and interpreting and recording EBT results.

(2) Only courses of instruction for operation of EBTs that are equivalent to the Department of Transportation model course, as determined by the National Highway Traffic Safety Administration (NHTSA), may be used to train BATs to proficiency. On request, NHTSA will review a BAT instruction course for equivalency.